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EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	**PAPER NUMBER**
3774	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,439	GANZ ET AL.	
	Examiner	Art Unit	
	Ann Schillinger	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-102, 104-156* is/are pending in the application.

4a) Of the above claim(s) *1-92, 123-148* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *93-102,104-122 and 149-156* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 152 and 155 are rejected under 35 U.S.C. 102(e) as being anticipated by Ashman et al. (US Pat. No. 6,413,089). Ashman et al. discloses claim 152 as follows: a bone graft (6) shaped and dimensioned to fill a recess around a base of an endosseous implant, wherein the bone graft comprises rigid porous synthetic material (col. 5, lines 24-65), wherein the bone graft comprises an internal cavity (where element 26 fits through 6) closely approximating but larger than the base of the endosseous implant and comprises an external configuration (outer surface of 6) closely approximating but smaller than the recess around the base of the endosseous implant. Please also see Figure 6.

Ashman et al. discloses the limitations of claim 155 in col. 5, lines 24-65.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 93-96, 98-102, 104-120,150, and 156 are rejected under 35 U.S.C. 103(a) as being anticipated by Tormala et al. (U.S. Pat. No. 5,084,051). Tormala et al discloses the following of claim 93: a bone graft wherein the bone graft is shaped and dimensioned to fill a recess around a base of an endosseous implant (col. 19, lines 56 through col. 20, lines 10), and wherein the bone graft comprises rigid porous synthetic material (col. 2, lines 28-34; col. 18, lines 19-24). Regarding the added claim language from the amendments, where the bone graft is to be placed around the base of an endosseous implant, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham,* 2 USPQ2d 1647 (1987).

Tormala et al discloses the limitations of claim 94 as shown in Figures 4, 6a-6c, 7a-7d.

Tormala et al discloses the separate pieces (1, 2) of claim 95.

Tormala et al discloses the following of claim 96: the bone graft of claim 93, wherein the bone graft comprises a central hole (hole where label "2" is located on Figure 7b).

Tormala et al discloses the following of claim 98: the bone graft of claim 93, wherein the bone graft is substantially axisymmetric (an axis through the top of Figures 7a-7d would have axisymmetric bone grafts).

Tormala et al discloses the following of claim 99: the bone graft of claim 93, wherein the bone graft is non-axisymmetric (an axis through the top of Figure 3 (right side) would have non-axisymmetric bone grafts).

Tormala et al discloses the limitations of claim 100 in col. 4, lines 67 through col. 5, lines 12.

Tormala et al discloses the following of claim 101: the bone graft of claim 330, wherein the dimensions of the region of deteriorated or resorbed bone are determined radiographically (col. 18, lines 37-39).

Tormala et al discloses the following of claim 102: the bone graft of claim 93, wherein the bone graft comprises a matrix of particles joined to each other forming a three-dimensionally interconnected network (col. 11, lines 2-9).

Tormala et al discloses the following of claim 104: the bone graft of claim 102, wherein the matrix has a porosity between approximately 0.2 and approximately 0.6 (col. 13, lines 28-30).

Tormala et al discloses the following of claim 105: the bone graft of claim 93, wherein the bone graft comprises nonresorbable material (col. 6, lines 41-42).

Tormala et al discloses the following of claim 106: the bone graft of claim 93, wherein the bone graft comprises hydroxyapatite (col. 18, lines 19-24).

Tormala et al discloses the following of claim 107: the bone graft of claim 93, wherein the bone graft comprises resorbable material (col. 6, lines 41-42).

Tormala et al discloses the following of claim 108: the bone graft of claim 93, wherein the bone graft comprises both nonresorbable and resorbable substances (col. 16, lines 15-20).

Tormala et al discloses the following of claim 109: the bone graft of claim 93, further comprising channels, which go into an interior (in Figure 2c, channels that screws, R, go through).

Tormala et al discloses the following of claim 110: the bone graft of claim 93, further comprising channels or patterns on a surface (see Figure 3 (right side)).

Tormala et al discloses the following of claim 111: the bone graft of claim 93, wherein the bone graft comprises a surface having a surface geometry (1) which is different from a geometry at an interior (2) (see Figure 3 (right side)).

Tormala et al discloses the following of claim 112: the bone graft of claim 93, wherein the bone graft comprises a surface having a surface composition which is different from a composition at an interior (see Figure 3; col. 10, lines 39-41).

Tormala et al discloses the following of claim 113: the bone graft of claim 93, wherein the bone graft comprises a surface having a surface geometry suitable to face natural bone (see Figure 2c).

Tormala et al discloses the following of claim 114: the bone graft of claim 93, wherein the bone graft comprises a surface having a surface composition suitable to face natural bone (see Figure 2c; col. 10, lines 40-43)

Tormala et al discloses the limitations of claim 115 in col. 19, lines 56-61; col. 20, lines 6-8.

Tormala et al discloses the limitations of claim 116 in col. 1, lines 49-55; col. 5, lines 65 through col. 6, line 4.

Tormala et al discloses the limitations of claim 117 in col. 4, lines 19-21; see Table 1.

Tormala et al discloses the following of claim 118: the bone graft of claim 117, wherein the polymer is a comb polymer (see Table 1, where polyurethane is listed).

Tormala et al discloses the following of claim 119: the bone graft of claim 117, wherein the polymer is resorbable (see Table 1).

Tormala et al discloses the following of claim 120: the bone graft of claim 117, wherein the polymer is non-resorbable (col. 1, lines 45-53).

Tormala et al discloses the following of claim 150: the bone graft of claim 93, wherein the bone graft comprises tricalcium phosphate (col. 1, line 21).

Tormala et al. discloses the limitations of claim 156 in col. 4, lines 19-58.

Claims 97 and 149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in view of Kuslich et al. (U.S. Pat. No. 5,899,908). Tormala et al. disclose the invention substantially as claimed, however, Tormala et al. has holes in some implant, but does not disclose a bone graft with an inside diameter larger the outside diameter. Kuslich et al. teaches in the same field of endeavor having a hole (16, 17) and an inside diameter greater than the outside diameter by less than about 0.5 mm in col. 13, lines 18-19, 41-42, and col. 7, lines 41-48, 52-59, for the purpose of enabling the implant to more easily receive tools that will properly insert the implant into the patient (col. 5, lines 9-14). Therefore, it would have been

obvious to one of ordinary skill in the art at the time the invention was made to make the inside diameter larger than the outside diameter in order to allow the implant receive tools that will properly insert the implant into the patient.

Tormala et al. disclose the invention substantially as claimed, however, Tormala et al does not disclose adapting the bone graft to receive a tool. Kuslich et al. teaches in the same field of endeavor, adapting the bone graft for receiving a tool, thus giving them a known relationship, in col. 2, lines 20-27 and col. 4, lines 61-67 for the purpose of more easily using the tool to insert the bone graft. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the bone graft to receive a tool in order to more easily use the tool to insert the bone graft.

Claim 121 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in view of Ducheyne et al. (U.S. Pat. No. 5,591,453). Tormala et al. disclose the invention substantially as claimed, however, Tormala et al does not disclose making sure the bone graft is sterile. Ducheyne et al. teaches sterilizing the graft in col. 1, lines 24-35 for the purpose of making material non-toxic and non-immunogenic. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to sterilize the bone graft in order to make the material non-toxic and non-immunogenic.

Claim 122 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in view of Sherwood et al. (U.S. Pub. No. 2003/0114936). Tormala et al. discloses the invention substantially as claimed, however, Tormala et al does not disclose three dimensional printing to formulate the pores on the bone graft. Sherwood et al. teaches in the same field of endeavor, three-dimensional printing for the purpose of better controlling the pore size (paragraphs 0051,

0052). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use three dimensional printing to make the pores in order to better control the pore size.

Claim 151 is rejected under 35 U.S.C. 103(a) as being anticipated by Sherwood et al. (U.S. Pat. No. 6,454,811). Boyce et al. discloses the following of claim 151: a bone graft for filling a recess around an endosseous implant base, said bone graft being manufactured by a method which comprises: spreading successive layers of a powder and three dimensionally printing an article to at least approximately the dimensions of the recess around the endosseous implant base.

Claim 153 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ashman et al. in view of Sherwood et al. (U.S. Pub. No. 2003/0114936). Ashman et al. discloses the invention substantially as claimed, however, Ashman et al does not disclose three dimensional printing to formulate the pores on the bone graft. Sherwood et al. teaches in the same field of endeavor, three-dimensional printing for the purpose of better controlling the pore size (paragraphs 0051, 0052). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use three dimensional printing to make the pores in order to better control the pore size.

Claim 154 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ashman et al. in view of Kuslich et al. (U.S. Pat. No. 5,899,908). Ashman et al. disclose the invention substantially as claimed, however, Ashman et al does not disclose adapting the bone graft to receive a tool. Kuslich et al. teaches in the same field of endeavor, adapting the bone graft for receiving a tool, thus giving them a known relationship, in col. 2, lines 20-27 and col. 4, lines 61-

67 for the purpose of more easily using the tool to insert the bone graft. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the bone graft to receive a tool in order to more easily use the tool to insert the bone graft.

Response to Arguments

Since claim 103 has been cancelled, the 35 USC § 112 rejection against it is withdrawn.

Applicant's arguments filed 8/21/2007 have been fully considered but they are not persuasive. As stated above, the added limitations only address the intended use of the bone graft, and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham,* 2 USPQ2d 1647 (1987).

Regarding, Kuslich et al. it is being interpreted that by shaping the bone graft to appropriately fit together with the tool, the graft and the tool will inherently have known relationship dimensions. Please also see the rejections given above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
October 28, 2007

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